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EXAMINER

KEYS, ROSALYND ANN

ART UNIT

PAPER NUMBER

1621

DATE MAILED: 12/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/626,178

Applicant(s)

SURBURG ET AL.

Examiner

Rosalynd Keys

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-24 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 17-24 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 09/988,860.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Status of Claims

1. Claims 17-24 are pending.
Claims 17-24 are rejected.
Claims 1-16 are cancelled.

Priority

2. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. 09/988,860, filed on November 21, 2001. The status of Application No. 09/988,860 needs to be included in the specification.

Specification

4. The abstract of the disclosure is objected to because the term acyclic is used to describe ethers which are not acyclic, but alicyclic. Acyclic compounds do not have cyclic groups in their structure. The rhinologically active substances of the instant invention all have a monocyclic group in their structure, i.e. R³ is disclosed as a monocyclic carbon system having 5, 6, 7 or 8 carbon atoms. Correction is required. See MPEP § 608.01(b).
5. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.
6. The disclosure is objected to because of the following informalities: in paragraph 00013 it is disclosed that "the inventive ethers do not have a cyclic structure like 1,8-cineole (eucalyptol), but have an acyclic structure". However, the instant compounds do have a cyclic structure (see R³). Also in paragraph 00018 the inventive rhinologically active substances are identified as acyclic ethers, however, they are not acyclic ethers but alicyclic ethers.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 20, 23 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Claim 20 is indefinite because the preparation should comprise the rhinologically active substance not the rhinologically active substance comprise the preparation.

10. Claim 23 is indefinite because of the phrase "a process claim 22". It should be rewritten to state "a process according to claim 22".

11. Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). The term "acyclic" in claim 24 is used by the claim to mean "alicyclic, i.e., relating or designating chemical compounds having both aliphatic and cyclic structures or characteristics", while the accepted meaning is "having an open-chain molecular structure rather than a ring-shaped structure." The term is indefinite because the specification does not clearly redefine the term.

12. Claim 24 is further indefinite because of the compound 1-(3,3-dimethylcyclohexyl)ethyl methyl ethyl. It would appear from the specification that the compound should be 1-(3,3-dimethylcyclohexyl)ethyl methyl ether (see paragraph 00060 of the instant specification).

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claims 17-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Jarboe et al. (US 3,128,772).

Jarboe et al. teach flavoring additives for tobacco products which impart a cooling sensation to the smoker when the tobacco is smoked (see entire disclosure, in particular column 1, lines 25-30). The additives are menthyl ethers (see column 1, line 40 to column 5, line 55). The menthyl ether content is between 0.01 to 1.0% by weight of the smoking tobacco product (see column 5, lines 59-62).

15. Claims 17, 18, and 20-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Garlick, Jr. et al. (US 5,695,746) or Pensak et al. (US 3,947,570A).

Garlick, Jr. et al. teach a liquid dentifrice comprising anethole, which is a compound having the claimed formula, wherein the dentifrice is disclosed to maintain the cooling and freshness attributes of menthol without bitterness or burning (see entire disclosure, in particular claims 1-14). The anethole compounds of Garlick, Jr. et al. would inherently provide the cooling and refreshing feeling to the pharyngeal or nasal cavity, since the compounds of Garlick, Jr. et al. have the same chemical formula and are utilized in the same manner, i.e., orally.

Pensak et al. teach a mouthwash having a stimulating and refreshing taste of lemon (see entire disclosure, in particular column 1, lines 8-15). Materials useful in mouthwash include anethole, which is a compound having the claimed formula (see column 1, lines 48-68).). The anethole compound of Pensak et al. would inherently provide the cooling and refreshing feeling

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to the pharyngeal or nasal cavity, since the compounds of Pensak et al. have the same chemical formula and are utilized in the same manner, i.e., orally.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

16. Claims 17, 18, and 20-22 are rejected under 35 U.S.C. 102(e) as being anticipated by Hanke (US 6,231,900 B1).

Hanke teaches a confectionary product and preparation having the claimed formula, wherein R¹ is as claimed, R³ is an alkyl substituted cyclohexyl and x is 0 (see entire disclosure, in particular column 1, lines 10-30; column 2, lines 4-6; column 2, line 26 to column 3, line 15; column 4, lines 1-24; column 7, lines 41-45 and examples 1 and 2). The confectionary product is disclosed as being in various forms including hard and soft candies, chewing gum and pastilles (see column 2, lines 32-35). The cooling agent is present in an amount from about 0.01 to about 15% (see column 5, lines 41-45). The products have good throat soothing properties (see column 1, lines 5-9).

Claim Rejections - 35 USC § 103

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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18. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

19. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

20. Claims 17 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hanke (US 6,231,900 B1).

Hanke disclose the invention as described above but fail to specifically disclose the compounds of claim 19. However, although not explicitly taught the menthyl ether compounds of the instant claims are clearly suggested by Hanke.

21. Claims 17, 18 and 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thomas et al. (US 3,993,604).

Thomas et al. teach alicyclic compounds having the claimed formula, wherein R¹ is as claimed, R² is hydrogen, R³ is an alkyl or alkenyl substituted cyclohexyl and x is 1 (see column 1, lines 6-45; column 3, lines 15-41; and examples 6 and 7). The claimed method is

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inherently taught since the compounds of Thomas et al. when digested in the foodstuffs disclosed by Thomas et al. would necessarily perform the claimed method.

The alicyclic compounds of Thomas et al. differ from the claimed compounds in that R² is hydrogen instead of methyl as claimed.

One having ordinary skill in the art at the time the invention was made would have found the instant invention obvious over the teachings of Thomas et al. since, it is well established that the substitution of methyl for hydrogen on a known compound is not a patentable modification absent unexpected or unobvious results. *In re Lincoln*, 126 USPQ 477, 53 USPQ 40 (CCPA 1942); *In re Druey*, 319 F.2d 237, 138 USPQ 39 (CCPA 1963); *In re Lohr*, 317 F.2d 388, 137 USPQ 548 (CCPA 1963); *In re Hoehsema*, 399 F.2d 269, 158 USPQ 598 (CCPA 1968); *In re Wood*, 582 F.2d 638, 199 USPQ 137 (CCPA 1978); *In re Hoke*, 560 F.2d 436, 195 USPQ 148 (CCPA 1977); *Ex parte Fauque*, 121 USPQ 425 (POBA 1954); *Ex parte Henkel*, 130 USPQ 474, (POBA 1960).

Thomas et al. further differ from the instant invention in that Thomas et al. fail to teach the use of the compound in amounts less than 0.05%.

One having ordinary skill in the art at the time the invention was made would have found the instant invention obvious over the teachings of Thomas et al. since, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 105 USPQ 233, 235 (CCPA 1955).

Response to Arguments**Hanke (US 6,231,900 B1)**

22. Applicants' arguments filed July 24, 2003 have been fully considered but they are not persuasive. The Applicants' argue that Hanke does not teach the possibility that its composition can create a feeling in an area of the body that the composition does not come into actual contact with. Hanke does not disclose any property of the cooling agents that includes the ability to provide a cooling-refreshing and clearing feeling in the throat, pharyngeal cavity, nasal cavity, and airways (areas that the composition, placed in the mouth, would come into contact with). As taught by Hanke, the known properties of the described compounds have the desired effect only on/in the mucous membrane of the mouth where actual contact is made between the composition and the tongue (see column 3, lines 40-42). The Examiner disagrees. Hanke teach that his compounds have good throat soothing properties (see column 1, lines 5-9). Further, the compounds disclosed by Hanke are the same as the instant compounds and are applied in the same manner, i.e., orally. Thus, Hanke inherently teaches the claimed invention.

Conrad et al. (US 4,130,509)

23. Applicant's arguments with respect to Conrad et al. have been considered but are moot since this reference is not being applied to the instant claims.

Thomas et al. (US 3,993,604)

24. The Applicants argue that the process of Thomas et al. is not directed to an ability to create a clearing refreshing feeling. This argument is not persuasive because under the principles of inherency, if a prior art device, in its normal and usual operation, would necessarily perform the method claimed, then the method claimed will be considered to be anticipated by the prior art device. When the prior art device is the same as a device

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described in the specification for carrying out the claimed method, it can be assumed the device will inherently perform the claimed process. *In re King*, 801 F.2d 1324, 231 USPQ 136 (Fed. Cir. 1986) (The claims were directed to a method of enhancing color effects produced by ambient light through a process of absorption and reflection of the light off a coated substrate. A prior art reference to Donley disclosed a glass substrate coated with silver and metal oxide 200-800 angstroms thick. While Donley disclosed using the coated substrate to produce architectural colors, the absorption and reflection mechanisms of the claimed process were not disclosed. However, King's specification disclosed using a coated substrate of Donley's structure for use in his process. The Federal Circuit upheld the Board's finding that "Donley inherently performs the function disclosed in the method claims on appeal when that device is used in normal and usual operation ' " and found that a prima facie case of anticipation was made out. *Id.* at 138, 801 F.2d at 1326. It was up to applicant to prove that Donley's structure would not perform the claimed method when placed in ambient light.). In the instant case the compounds of Thomas et al. are disclosed as being useful in foodstuffs. Thus, since the compounds of Thomas et al. are essentially the same as the instant compounds then upon digestion, i.e., their normal and usual operation, the compounds of Thomas et al. would necessarily impart a clearing feeling to the pharyngeal or nasal cavity.

Allowable Subject Matter


25. Claim 24 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

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26. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosalyn Keys whose telephone number is 571-272-0639. The examiner can normally be reached on M and F 3:00-8:00 pm and T-TR 5:30-10:30 am.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Rosalyn Keys
Primary Examiner
Art Unit 1621

December 4, 2005